

WEST et al
Appl. No. 10/524,048
October 18, 2007

REMARKS/ARGUMENTS

Reconsideration of this application and entry of the foregoing amendments are respectfully requested.

The claims have been revised to define the invention with additional clarity. For example, claim 1 has been amended to make clear that the invention relates to compounds of Formula 1. Claim 1 as presented in the Preliminary Amendment filed February 8, 2005 makes it clear that OR is an ether type moiety. Thus, R is an ether type of moiety (eg, alkyl ether) and cannot be linked to another sugar (for support, see page 7, lines 7-10 of the PCT as filed). Claim 1 has been further amended to include substituents as recited in claim 5 as filed. Claim 4 has been amended to conform with claim 1 as amended under Article 34. Claim 5 has been revised to depend from any one of claims 1-4. Claims 6-24 have been revised so as to be drawn to a method. Minor errors in the claims (including omission of periods) have been corrected. The claims as presented are fully supported by an enabling disclosure.

Claims 1-27 stand rejected under 35 USC 101 as allegedly lacking utility. Withdrawal of the rejection is submitted to be in order for the reasons that follow.

The Examiner acknowledges that the description states that the class of compounds as claimed could be used as a library for performing high-throughput screens for drug discovery.

One skilled in the art would appreciate the range of biological activities associated with this class of compounds as well as the types of screens to be performed.

To support their position, Applicants submit concurrently herewith an Information Disclosure Statement making of record selected references (which include documents referenced in the application) that one skilled in the art would have been aware of disclosing expected activities and types of screens to use.

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For example, Gruner discloses use of carbohydrate-based mimetics in drug design. The mimetics include a somatostatin agonist, and successively a NK-1 receptor antagonist (see page 499; Figure 7). The mimetics represent a fully oxygenated pyranose scaffold. Furthermore, the tetrasubstituted xylofuranose 63 was synthesized by Papageorgiou as a potential nonpeptide mimic of somatostatin (Figure 8; page 500).

WO 9511686 discloses, in Example 14, the affinity of compounds for a variety of G-protein linked receptors. Standard protocols for testing of the compounds against G-protein linked receptors are also disclosed. The compounds represent peptide mimetics or analogs and are similar to compounds of the present invention insofar as the monosaccharide scaffold is concerned. All of the positions of the scaffold are fully oxygenated. Similarly, see also Hirschmann JACS (1992).

Applicants' invention is based, at least in part, on the premise that the addition of at least a nitrogen atom in the scaffold, at the 2-position, for example, enhances the activity of the monosaccharides, thereby providing a surprising result.

As will be clear from a review of the references, the compounds were tested with a number of biological activities, including GPCR and somatostatin. The disclosure of this prior art in the instant application further substantiates Applicants' assertion that the utility requirements of 35 USC 101 are met.

Thus, the present invention provides new compounds which overcome the limitations of the prior art and provides compounds with improved biological properties. Compounds of the invention are suitable for testing as drug candidates in a range of biological systems, particularly those receptors which interact with peptide ligands. Examples include NK-1 receptor, somatostatin receptors, integrin receptors and endothelin receptors.

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In view of the above, reconsideration is requested.

Claims 1-27 stand rejected under 35 USC 112, first paragraph, as the one would allegedly not know how to use the claimed invention. Withdrawal of the rejection is submitted to be in order for the reasons set forth above in rebutting the rejection under 35 USC 101.

Reconsideration is requested.

Claims 6-21 stand rejected under 35 USC 112, second paragraph, as allegedly being indefinite. Withdrawal of the rejection is submitted to be in order in view of the above-noted claim revisions. Reconsideration is requested.

Claims 1-27 stand rejected under 35 USC 112, second paragraph, as allegedly being indefinite. Withdrawal of the rejection is in order for the reasons that follow.

Claim 1 has been amended to be limited to "compounds of formula 1" - the reference to "a derivative of a furanose and pyranose form of a monosaccharide" has been deleted.

Claim 1 has been amended to limit the compounds of formula 1 to monosaccharides by importing the proviso from claim 5 that "the group R may not be or contain another saccharide moiety".

The term optionally substituted has been defined by incorporating the definition from claim 5 into claim 1.

Furthermore, the terms "heteroalkyl, heteroaryl and heteroarylalkyl" are limited to C1 to C15 heteroalkyl, C6 to C15 heteroaryl, or C6 to C15 heteroarylalkyl.

Applicants respectfully submit that the claims as amended are definite. Withdrawal of the objection is requested.

Claims 1, 2 and 4 stand rejected under 35 USC 102(b) as allegedly being anticipated by Christ et al. The rejection is traversed.

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The compounds disclosed in Christ et al are disaccharides and do not fall within the scope of claim 1 as presented. Accordingly, withdrawal of the rejection is requested.

Claims 1, 3 and 26 stand rejected under 35 USC 102(e) as allegedly being anticipated by Lin et al. This citation discloses a substituted disaccharide at page 2. The compounds are known as peptide antibiotics AA-896. Applicants submit that none of the compounds disclosed in this citation fall within the scope of claim 1 as presented.

Withdrawal of the rejection is requested.

Claim 27 stands rejected under 35 USC 103 as allegedly being obvious over Lin et al. The rejection is traversed.

Lin et al, as discussed above, discloses peptide antibiotics based on a disaccharide moiety. These compounds are structurally complex and significantly different from the compounds of the present invention. No motivation would have been found in Lin et al to prepare the monosaccharides of the claimed invention. Accordingly, withdrawal of the rejection is requested.

Claims 1, 2, 4, and 22-26 stand rejected under 35 USC 103 as allegedly being obvious over Hanessian et al in view of Carey et al (the Action reads "anticipated" but "obvious" was clearly intended). The rejection is traversed.

Hanessian et al discloses the immobilization of carbohydrates and other related compounds onto a solid support through the formation of a 1,3-benzylidene acetal. Once supported, Hanessian demonstrates the effective cleavage of these compounds from the solid support. Two examples of amino sugars are described, one with a carbobenzyloxy protecting group (CbzHN) and the other with a phthalimido protecting group (NPhth).

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It will be appreciated that the solid support is a high molecular weight, insoluble polymer which falls outside the definition of R in Claim 1 – this being “C1 to C9 alkyl, C1 to C15 alkenyl, C1 to C15 alkynyl, C1 to C15 heteroalkyl, C6 to C15 aryl, C6 to C15 heteroaryl, C6 to C15 arylalkyl or C6 to C15 heteroarylalkyl”

Carey et al describes a range of other protecting groups that can be used in place of a carbobenzyloxy (CbzHN) moiety to protect an amine.

Neither Hanessian et al nor Carey et al, either alone or in combination, would have suggested compounds of claim 1 as presented. Neither Hanessian et al nor Carey et al, either alone or in combination, would have taught a skilled person how to prepare compounds of claim 1 as presented.

Claims 22 to 26 have been redrafted as method claims and depend from claim 1.

Applicants respectfully request withdrawal of the rejection.

Claims 1, 2, and 4 stand rejected under 35 USC 103 as allegedly being obvious over Fukase et al in view of Carey et al. The rejection is traversed.

Fukase et al disclose the synthesis of Lipid A, a complex immuno-stimulatory disaccharide. Neither Lipid A nor the advanced intermediates to Lipid A in schemes 1, 4 or 5, fall within the scope of the instant claims nor would the reference have suggested the instant invention. The simpler compounds, in schemes 2 and 3, are also outside the scope of claim 1 as amended.

The Examiner specifically points to compounds 3 and 14 of scheme 3 as falling within the scope of claim 1. Applicants respectfully submit that claim 1 does not include compounds in which R4 and R5 combine to form a cycle, viz “the groups R1 to R5 may not combine together to form a cycle”.

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Compound 3 also falls outside the scope of the instant invention because the R group at R3 is a heteroalkyl moiety of more than 15 carbons. Moreover, Fmoc moiety is excluded at R2.

The Examiner contends that Carey et al teaches alternatives to the Fmoc group and that the invention would have been obvious over Carey et al and Fukase et al. The definition of N(Y)Z in claim 1 as presented excludes the carbamoyl functionality at any position.

Applicants respectfully submit that, in view of the above, the instant invention would not have been obvious over Fukase et al and Carey et al. Withdrawal of the rejection is requested.

Claims 1, 2 and 4 stand provisionally rejected as allegedly representing obviousness type double patenting over claims of U.S. Application No. 10/419,070. The rejection is traversed.

R4 and R5 in the cited application recite formation of benzylidene acetal. Applicants submit these compounds do not fall within the scope of the present claims because R4 and R5 do not form a ring as stated above. Because R4 and R5 cannot form a ring structure, benzylidene moieties fall outside the scope of the instant invention.

Applicants respectfully request withdrawal of the rejection.

An Information Disclosure Statement is being filed concurrently herewith. The Examiner is requested to initial and return the PTO/SB/08a Form.

This application is submitted to be in condition for allowance and a Notice to that effect is requested.

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Respectfully submitted,

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